DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-66

July 11, 2000

Mr. Alan R. Figueroa
President and CEO
Catalysis Corporation
8185-2 N.W. 155th Street
Miami Lakes, Florida 33016

Dear Mr. Figueroa:

This letter is in reference to your firm's marketing and distribution of the products, Blue Cap, Kalsis, Herpigen spray, Herpigen lip cream, Viusid, and Diamel. Labeling for these products makes therapeutic claims which cause the products to be drugs [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act]. Labeling is not limited to the immediate product containers, but includes all promotional material, printed or otherwise, connected to the products which you distribute.

Blue Cap spray, cream and shampoo are labeled as containing the active ingredient, zinc pyrithione. These products are sold over-the-counter (OTC) and promotional material for these products offers them for the treatment of dandruff, seborrheic dermatitis, and psoriasis.

Blue Cap products are subject to final regulations on Drug Products for the Control of Dandruff, Seborrheic Dermatitis and Psoriasis [Title 21, Code of Federal Regulations, Section 358.701 to 750] that became effective on December 4, 1992. This product fails to meet all the requirements of the final regulations. Since a claim for psoriasis treatment is not permitted for the active ingredient, zinc pyrithione, the product is a new drug [section 201(p) of the Act]. A new drug may not be legally marketed in the United States without an approved New Drug Application [section 505(a) of the Act]. These products are also misbranded since the labeling does not include the complete "statement

of identity" and adequate directions for the condition for which it is offered [section 502(f)(1) of the Act]. The labeling for these products is false and misleading because it suggests that the products are safe and effective for their intended uses, when in fact, this has not been established [section 502(a) of the Act].

Furthermore, Blue Cap spray and cream are adulterated because FDA laboratory analysis confirmed the presence of undeclared corticosteroids, i.e., betamethasone 17-propionate 21-butyrate in the spray product and betamethasone 17-propionate 21-stearate in the cream product. The presence of either of these corticosteroid active ingredients in an OTC product causes the article to be a new drug which is not approved by FDA for sale in the United States as well as causing it to be adulterated [section 501(c) of the Act]. Also, these products are misbranded [section 502(e)(1)(A)(ii) of the Act] since the label fails to bear the established name of each active ingredient.

Objectionable claims for the other products include the following:

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| Kalsis | "osteoporosis treatment," "improve and accelerate the reconstruction of the bone structure," "results have been confirmed by densitometry in osteoporosis patients"; |
| Herpigen Spray and Lip Cream | "genital herpes simplex virus," "alternative medicine product," "all natural alternative to treating intimate problems with a prescription," "maximum effectiveness for the most intimate problems," "all natural drug free product," "clinical studies available upon request";<br><br>The product name "Herpigen" associated vaginal or lip products represents an implied Herpes claim. |
| Viusid | "increase of the immunological defenses in all those processes that cause immunodeficiencies," "eliminate the negative effects of the free radicals that appear in all the infectious processes," antiviral, reduces the infections, helps with...healing of wounds, |

antitumoral, treatment of gastic hyperactivity, protects against cancerigenic agents, prevention of many viral and bacterial infections, HIV, prevents appearance of buccal ulcers, analgesic, cicatrization [healing or scar formation] of wounds;

Diamel — All references to diabetes or diabetics including those found in the bibliography, glucemia, regenerate the production of insulin, "my glucose level went down from 380 to an average of 100/103...My insulin level also went down," "Natural Drug Free Formula," "Natural Medicine Breakthrough Product," "clinical studies available upon request".

These products are "new drugs" [section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications (NDAs) [section 505(a) of the Act].

These drugs are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [section 502(f)(1) of the Act] and their labeling is false and misleading because it suggests that the products are safe and effective for their intended uses when in fact, this has not been established [section 502(a) of the Act].

This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct these violations and to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to the Food and Drug Administration, Florida District office, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, Attention: Martin E. Katz, Compliance Officer.

Sincerely,

Emma R. Singleton
Director, Florida District